

## REMARKS

### **I. STATUS OF THE CLAIMS**

Claim 2-13 and 17 were pending at the time of the Action with claims 18-29 withdrawn from consideration. Claims 18-29 are canceled. Claims 2 and 5 are amended. Support for these amendments can be found in the claims as originally filed and in the specification on page 3, lines 18-20. No new matter has been added. Claims 2-13, and 17 are currently pending and in condition for allowance.

### **II. REJECTIONS UNDER 35 USC § 112**

The Action rejects claims 2-13, and 17 under 35 U.S.C. §112 first paragraph as lacking enablement. To advance prosecution of the currently claimed invention, Applicants have clarified the pending claims, without prejudice. Applicants reserve the right to pursue any canceled subject matter in a continuation or divisional application. The present claims are directed to lipoasparagine, wherein  $R^1$  and  $R^2$  are each, independently, a linear, branched, saturated and/or unsaturated hydrocarbon; or a combination thereof, wherein  $R^1$  is a hydrocarbon of at least 5 carbon units; and X is an O group or a  $CH_2$  group. In light of the currently pending claims this rejection is moot because the claims are directed to lipoasparagine and do not include reference to a cholesterol, steroid, or aromatic moiety.

### **III. REJECTIONS UNDER 35 U.S.C. §102**

Claims 2, 4, 11, and 13-17 are rejected under 35 U.S.C. §102 as being anticipated by Chu *et al.* (1992).

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

*Chu et al.* does not describe each and every element the pending claims. Applicants note the R<sup>1</sup> group of the structures claimed in claim 2 is selected from “a linear, branched, saturated and/or unsaturated hydrocarbon; or a combination thereof, wherein R<sup>1</sup> is a hydrocarbon of at least 5 carbon units.” The *Chu et al.* reference is directed solely to a four carbon tert-butyl group at R<sup>1</sup>. Applicants request withdrawal of the rejection.

#### IV. REJECTIONS UNDER 35 U.S.C. §103

Claims 2-7, 11, and 13-17 are rejected under 35 U.S.C. §103 as being obvious in light of *Chu et al.* (1992). Applicants traverse.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) *must teach or suggest all the claim limitations*. The reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As described above, the *Chu et al.* reference does not teach all of the claim limitations of the currently pending claims, especially a structure within the genus claimed. Furthermore, the suggestion or motivation to modify the compound synthesized in *Chu et al.* is deficient and is at least impermissible hindsight. The only mention of an alleged obviating compound in *Chu et al.* is shown as an intermediate in the synthesis of compound 1. And even then the compound is not within claimed genus, see presently pending claims. *Chu et al.* provides nothing to suggest or motivate one of skill to produce a fatty acid derivative with a hydrocarbon of at least 5 carbons at the R<sup>1</sup> position, in fact the R<sup>1</sup> position in the *Chu et al.*, reference is invariably a four carbon tert-

butyl group. Furthermore, there is no suggestion or discussion of any physical properties associated with the intermediate in *Chu et al.*

The Federal Circuit has recently addressed an analogous issue in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Pharmaceutical Inc.*, 520 F.3d 1358. The court in *Ortho-McNeil* upheld a lower court finding of non-obviousness of the chemical topiramate because the discovery of such a chemical is not within the scope of the *KSR International Co. v. Teleflex Inc.* proposition that "[w]hen there is a design need or market pressure to solve a problem and there are a **finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue** the known options within his or her technical grasp." 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007) (emphasis added). As the court states in *Ortho-McNeil* "KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. . . [t]he ordinarily skilled artisan would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate. Even beyond that, the ordinary artisan in this field would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes). In sum, this clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness. *Id.* at 1742." The present case presents the same situation. The Action does not establish any reason as to why one of skill in the art would have chosen such alternatives at either the R<sup>1</sup> and/or R<sup>2</sup> positions. The only suggestion of pursuing such alternatives is found in the present application and this is not permitted. Applicants respectfully

request the reconsideration of the rejection and the consideration of Applicants' good-faith effort to advance prosecution. Withdrawal of the rejection is respectfully requested.

## V. CONCLUSION

Applicants believe that the present document is a full and complete response to the final Action dated March 21, 2008. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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